

## Remarks

### The Interview

The undersigned and applicants greatly appreciate the interview on March 13, 2007, with the examiner and his supervisor. This provided an opportunity to explain not only the features of the claimed invention, but to review what is believed to be the closest art (that discussed in the background of the invention at page 2, relating to 3-polyhydroxybutyrate, not the claimed 4-hydroxybutyrate porous polymeric nerve conduits), and the comparative evidence in the examples showing the significantly greater rate of nerve regeneration obtained with the claimed nerve regeneration conduit. See example 5, pages 9-10, showing a nerve regeneration rate of at least 1 mm/day.

As the prior art in the background of the invention demonstrates, nerve conduits are well known to those skilled in the art. Applicants have not invented nerve conduits *per se*, but a greatly improved nerve conduit, formed of a 4-polyhydroxybutyrate polymer with pores of between 5 and 500 microns in diameter. The best of the prior art devices only achieves a rate of 1 mm/**week**, not per day (page 3, line 1, and references cited therein).

It was understood that the prior art cited in the background adequately demonstrated that there was no enablement issue under 35 U.S.C. 112, for nerve conduits generally.

### Amendments to the Claims

As discussed during the interview, the claims were amended to more specifically exclude general references to devices such as a multi-polymer braid, by incorporation of

"tube or sheet" and the diameter of the pores between 5 and 500 microns. Support is found at page 6. See also page 6, lines 24-27 for support of the size of the conduit which is implanted

Double Patenting/35 U.S.C. 102(b) Prior Art Rejections

As discussed during the interview, the prior art cited under the doctrine of double patenting and 35 U.S.C. 102, U.S. Patent Nos. 6,610,764, 6,838,493, 6,548,569, 6,867,247 and 7,179,883, U.S.S.N. 10/835,926 and 11/193,580, and WO 01/54593, all generally relates to polyhydroxyalkanoates in the form of various medical devices.

The prior art does not disclose nor make obvious the claimed nerve conduits:

Formed of 4-hydroxybutyrate polymer

Having pores between 5 and 500 microns in diameter

In the form of a tube or sheet

Which have an unexpectedly and significantly greater rate of nerve regeneration than the prior art 3-hydroxybutyrate or other polymeric nerve conduits.

Allowance of claims 1, 3-14, as amended, is respectfully solicited.

Respectfully submitted,

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